

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant(s): Gleave, et al. | |
| Application No.: 10/605,498 | Group Art Unit: 1635 |
| Filed: 10/2/2003 | Examiner: Amy Hudson Bowman |
| Title: Compositions and Methods for Treatment of Prostate and Other Cancers | Confirmation No: 2497 |
| Attorney Docket No.: UBC.P-031 | |
| Customer No.: 021121 | |

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

PETITION UNDER RULE 1.144.

Dear Sir:

This petition is filed in response to the Ex Parte Quayle Action of November 30, 2005, for the above-captioned application.

The present application originally contained claims directed generically to pharmaceutical composition comprising a therapeutic agent that reduces the expression of a protein hsp27. Examples of the therapeutic agent were provided as antisense oligonucleotides (as exemplified by Seq ID Nos. 1-82) and siRNA oligonucleotides (as exemplified by Seq ID Nos. 83-90).

In a restriction requirement mailed March 23, 2005, the Examiner characterized the pharmaceutical composition as one invention, and a method of treatment as another invention. Applicants elected the pharmaceutical composition invention of claims 14-24, and stated that recombination of the method claims would be appropriate if the composition claims were allowed.

The Examiner also stated that claims 5, 6, 10, 11, 18, 19, 23 and 24 were subject to an additional restriction because of they were not considered to be a proper Markush group. These claims listed specific sequences by Sequence ID nos that fell within the generic scope of the

Appln No.: 10/605,498
Amendment Dated: January 29, 2006
Reply to Office Action of November 30, 2005

original claim. The basis for the assertion of an improper Markush Group because each sequence was structurally unique. The Examiner therefore required election of one sequence from among those specifically listed. This election was made without traverse with the understanding that it was a species-type election, and that the generic claims and other species would be recombined and considered in the absence of prior art. However, in the Ex parte Quayle action, this has not been the case, and review of the the species/Markush group restriction is now requested.

In the response to the restriction requirement, Applicants amended claim 14 to refer only to oligonucleotide therapeutic agents. All of the sequences are species within this generic description. Applicants designated Seq. ID No. 82 as an elected species as set forth in claim 19.

In a first Official Action, the claims were rejected as failing to comply with the written description requirement, and as anticipated by various art references. These references, however, presented a form of anticipation which did not relate to any actual disclosure of any of the sequences within the scope of the claim, and an obviousness rejection that included no disclosure of oligonucleotide antisense species. After an amendment of the claims to specify a sequence (Seq. ID No. 91) as the target sequence in the generic claim, only these anticipation and obviousness rejections were maintained.

During an interview with Applicant's attorney, the Examiner explained that the claim interpretation that led to the anticipation rejection, indicating that she was interpreting the language as covering any consecutive series of bases, or any length, and giving no weight to the language indicating that the therapeutic agent was effective to reduce the amount of hsp27 in a cell. She also stated that the Horman reference was considered to show some utility for hsp27 antisense, and thus to provide a motivation to make oligonucleotides generally, but not for any oligonucleotide sequence specifically. The amendment of October 25, 2005 followed.

Applicants note that during the prosecution of this application, the Examiner has considered generic claims to hsp27 oligonucleotide antisense generally and to any antisense targeted to hsp27 as reflected by Seq. ID No. 91. The Examiner has also considered the specific sequence of Seq ID No. 82. In the course of this searching, the Examiner has not identified a single reference which discloses an antisense oligonucleotide targeted to hsp27. Yet now, after whittling down the scope of the claims to Applicants' specifically disclosed sequences, the examiner says no, there is no generic invention and you must file 89 more applications to obtain coverage from the genus. This is both unfair, and unjustified under any reasonable application of restriction practice.

Restriction is justified in circumstances where separate inventions are claimed **and** where the consideration of multiple inventions places a burden on the examiner. Where the claims were originally presented **and examined** as a generic claim that encompassed all that is now claimed,

Appln No.: 10/605,498
Amendment Dated: January 29, 2006
Reply to Office Action of November 30, 2005

it is not clear how there can be an argument that the claims are to different inventions. Furthermore, since the examiner has presented no evidence of finding even a single sequence for an hsp27-targeted antisense oligonucleotide after examination of the generic claims, it is not clear where the burden on the Examiner arises.

Art relating to oligonucleotides targeted to hsp27 is reasonably likely to refer to hsp27, and thus to be readily searchable. To the extent that one or more of the same sequences may exist in other contexts (a fact neither shown nor argued by the Examiner), this is still readily searchable. For years now, patent applicants have been required to spend time and money to provide sequence listings to the US Patent Office for every sequence over 10 bases or three amino acids in length, even when the sequence was already part of the prior art. Presumably this forms a database which is searchable by the examiner. Further, each of the sequences of this application had to be provided in computer readable form, and therefore should be easily input into a search system. Routine sequence searching is also available through other resources. Thus, at most the multiple sequence here would require someone to copy (or key in, if all of the sequence listing tasks imposed on applicants are nothing but make work) sequences into defined search engines. It is not a circumstance where there are inventions that have to be looked at in diverse art, merely a mechanical search. The apparent unwillingness and failure of the patent office or of the examiner to take advantage of the resources for performing such a search is not the type of "burden" that should justify a restriction requirement as imposed in this case.

Furthermore, it is apparent that the restriction requirement is not based on any actual assessment of burden, but is merely a requirement that is made because it can be made. For example, Seq ID No. 82 (the elected species) and Seq. ID No. 81 differ by only one base. The same type of one base difference is seen between Seq ID NOs. 79 and 80, while many of the other sequence overlap. For example, the first 11 bases of Seq ID No. 72 are the same as the last 11 bases of Seq ID No. 73.

Given all of these circumstances, Applicants submit that the restriction requirement as imposed by the Examiner and the effective requirement that Applicants pursue 90 different

Appln No.: 10/605,498

Amendment Dated: January 29, 2006

Reply to Office Action of November 30, 2005

applications is improper. Supervisory intervention and a direction to the examiner to consider all of the claims as presented in the amendment of October 26, 2005 are requested.

Respectfully submitted,

A handwritten signature in cursive script, reading "Marina T. Larson", with a long horizontal flourish extending to the right.

Marina T. Larson, Ph.D

Attorney/Agent for Applicant(s)

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